DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBSTANCE ABUSE AND MENTAL HEALTH SERVICES ADMINISTRATION
CENTER FOR SUBSTANCE ABUSE TREATMENT

Form Approved: OMB Number 0930-0206
Expiration Date: 09/30/2003
See OMB Statement on Reverse

Exception Request and Record of Justification Under 42 CFR § 8.11 (h)

DATE OF SUBMISSION

Note: This form was created to assist in the interagency review of patient exceptions in opioid treatment programs (OTPs) under 42 CFR § 8.11 (h).

Detailed INSTRUCTIONS are on the cover page of this form. PLEASE complete **ALL** applicable items on this form. Your cooperation will result in a speedy reply. Thank you.

BACKGROUND INFORMATION

Program OTP No: (Same as FDA ID) ☐☐ – ☐☐ , ☐☐☐ – ☐ **Patient ID No:** ☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Program Name: _____

Telephone: _____ **Fax:** _____ **E-mail:** _____

Name & Title of Requestor: _____

Patient's Admission Date: _____ **Patient's current dosage level:** _____ mg ___ Methadone ___ LAAM ___ Other: _____

Patient's program attendance schedule per week
(Place an "X" next to all days that the patient attends*): ___ **S** ___ **M** ___ **T** ___ **W** ___ **T** ___ **F** ___ **S**

*If **current** attendance is less than once per week, please enter the schedule: _____

Patient status: ___ Employed ___ Unemployed ___ Homemaker ___ Student ___ Disabled ___ Other: _____

REQUEST FOR CHANGE

Nature of request:
___ Temporary take-home medication ___ Temporary change in protocol ___ Detoxification exception ___ Other: _____

Decrease regular attendance to
(Place an "X" next to appropriate days*): ___ **S** ___ **M** ___ **T** ___ **W** ___ **T** ___ **F** ___ **S** **Beginning date:** _____

*If **new** attendance is less than once per week, please enter the schedule: _____

Dates of Exception: **From** _____ **to** _____ **# of doses needed:** _____

Justification: ___ Family Emergency ___ Incarceration ___ Funeral ___ Vacation ___ Transportation Hardship ___ Step/Level Change ___ Employment ___ Medical ___ Long Term Care Facility ___ Other Residential Treatment ___ Homebound ___ Split Dose ___ Other: _____

REQUIREMENTS

Regulation Requirements:

1. **For take-home medication:** Has the patient been informed of the dangers of children ingesting methadone or LAAM? ___ Yes ___ No ___ N/A
2. **For take-home medication:** Has the program physician determined that the patient meets the 8-point evaluation criteria to determine whether the patient is responsible enough to handle methadone as outlined in 42 CFR §8.12(i)(2)(i)-(viii)? ___ Yes ___ No ___ N/A
3. **For multiple detoxification admissions:** Did the physician justify more than 2 detoxification episodes per year and assess the patient for other forms of treatment (include dates of detoxification episodes) as required by 42 CFR §8.12(e)(4)? ___ Yes ___ No ___ N/A

Submitted by:

Printed Name of Physician	**Signature of Physician**	**Date**

APPROVAL

State response to request:

___ Approved ___ Denied _____ _____

State Methadone Authority **Date**

Explanation: _____

Federal response to request:

___ Approved ___ Denied _____ _____

Public Health Advisor, Center for Substance Abuse Treatment **Date**

Explanation: _____

Please fax to CSAT/OPAT, (301) 443-3994 or Email: otp@samhsa.gov

This exception is contingent upon approval by your State Methadone Authority (as applicable) and may not be implemented until you receive such approval.

Purpose of Form: This form was created to facilitate the submission and review of patient exceptions under 42 CFR § 8.11(h). This does not preclude other forms of notification.

Paperwork Reduction Act Statement